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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 17/08 — A1

(11) International Publication Number: **WO 00/33744**

(43) International Publication Date: 15 June 2000 (15.06.00)

(21) International Application Number: PCT/US99/29029

(22) International Filing Date: 8 December 1999 (08.12.99)

(30) Priority Data:

60/111,438	8 December 1998 (08.12.98)	US
60/121,371	25 February 1999 (25.02.99)	US
60/129,959	19 April 1999 (19.04.99)	US
60/143,251	9 July 1999 (09.07.99)	US

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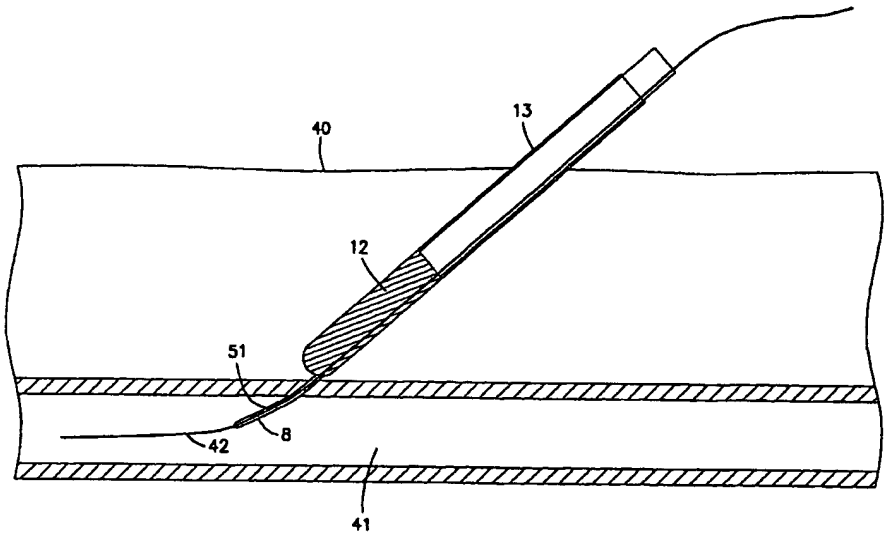
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: DEVICE AND TECHNIQUE FOR PERCUTANEOUS CLOSURE OF VASCULAR PUNCTURE SITES



(57) Abstract

The present invention includes a device for achieving hemostasis as part of an intravascular procedure. In one preferred embodiment the vessel is accessed, and a hemostatic composition is infused into the vessel puncture site. In other preferred embodiments, a hemostatic plug (12) is placed against the blood vessel wall (41) at the site of the puncture. Other preferred embodiments are methods of achieving hemostasis as part of an intravascular procedure with the use of hemostatic compositions, and plugs. The present invention includes the use of alginate compositions as hemostatic compositions, and plugs as part of intravascular procedures or other medical procedures.

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DEVICE AND TECHNIQUE FOR PERCUTANEOUS CLOSURE OF VASCULAR PUNCTURE SITES

The present application claims priority from U.S. Patent Applications Nos. 60/111,438, 60/121,371, 60/129.959, and 60/143,251, which are all hereby incorporated by reference in their entirety.

Field of the Invention

The present invention applies to techniques for achieving hemostasis after percutaneous arterial puncture for any purpose, including but not limited to diagnostic radiology and cardiology, as well as interventional radiology and interventional cardiology.

Background of the Invention

Certain medical procedures require intravascular access. In procedures such as cardiac catheterization, counterpulsation and angiography, a catheter or other device is inserted into an artery and fed through the vascular tree to the location of interest. Such procedures are performed most commonly by percutaneous methods, and the access site most usually selected is the groin, where the femoral artery is relatively accessible. However, other arterial access sites as well as venous access sites are intended to be encompassed by the scope of the present invention.

Such percutaneous procedures normally are performed by a Seldinger-type technique

consisting essentially of inserting an angiographic needle into the artery, followed by inserting a guide wire through that needle into the artery. Thereafter the needle is removed leaving the guide wire in place. Next, a sheath-dilator set is fed over the guide wire into the artery in order to re-establish a vascular access route and to enlarge the opening sufficiently to permit insertion of a catheter or other device. Thereafter, the dilator is removed and the sheath or guide cannula remains in place during the procedure. A catheter or other device then can be inserted through the cannula directly into the lumen of the artery.

After the procedure has been completed the catheter or other device, as well as the sheath, is removed and the wound must be closed. Normally this is achieved by the application of pressure to the skin and underlying tissue located above the vessel puncture site. This is commonly applied by direct digital pressure by a medical professional, by a pressure dressing or through the use of sandbags. With respect to arterial puncture sites, customarily pressure is applied for at least ½ hour, and frequently for much longer periods. During this period the patient must be immobilized, lest movement interfere with the sealing of the puncture site. Due to the amount of pressure required, the duration for which the pressure is required, and the mandatory immobilization, the procedure is uncomfortable and may be painful. Such patients also require the prolonged personal attention of a health-care professional. Finally, puncture sites closed in this manner can reopen unexpectedly a substantial period after wound closure apparently has been achieved, therefore patients often are required to remain under close observation for prolonged time periods, which can necessitate a hospitalization.

In an attempt to minimize such problems, physicians performing such procedures can utilize the smallest caliber devices, often however a larger caliber device may be preferable for many of these procedures. There is a need for an effective and simple means of achieving reliable vessel puncture site closure under these circumstance.

A series of devices have been developed in an attempt tc address these problems. Such devices attempt to achieve hemostasis through the application of a variety of means once the procedure has been completed. Examples include those devices described in U.S. Pat. Nos. 4,744,364, 4,852,568 and 4,890,612 to Kensey. These three patents describe a mushroom or umbrella shaped device which is used to seal the artery from the inside. The head of the device is placed within the arterial lumen and means are provided to pull and hold the underside of the head against the inside wall of the lumen. It is believed, however, that sealing from the inside can be the source of its own problems, including the promotion of clot formation inside the vessel. Another method for sealing a puncture wound after removal of a catheter is described in U.S. Pat. No. 4,929,246 to Sinofsky. The approach taken there is to insert a balloon-tipped catheter into the tissue wound, inflate the balloon against the hole in the artery and then use a laser to thermally weld the wound closed. Other approaches include applying hemostatic material around the puncture site after completion of the procedure as described in U.S. Pat, No. 5,437,631. U.S. Patent No. 5,478,352 to Fowler, describes a device and method for closing a puncture by inserting a plug into the wound. This is performed after the procedure is completed and the correct placement of the plug is achieved with the use of a balloon catheter or cylindrical insertion device. U.S. Patent No. 5,437,631 to Janzen describes a device for inserting collagen or other hemostatic materials into a puncture wound after a

blood vessel has been accessed and the puncture site enlarged by the insertion of a vascular stent or dilator. U.S. Patent No. 5,725,498 to Janzen describes the placement of hemostatic material against a punctured vessel wall after a procedure has been completed and requires compression of the blood vessel as a part of the placement of the hemostatic material. U.S. Patents Nos. 5,383,896 and 5,868,778 to Gershony et al. describe devices and methods to effect closure of a blood vessel puncture site after completion of a procedure requiring the insertion of an inflatable balloon device into the lumen of the blood vessel. U.S. Patents Nos. 4,838,280 and 5,080,655 to Haaga describe medical biopsy needles with bioabsorbable gelatin tips and U.S. Patent No. 4,936,835 to Haaga describes a medical needle with a bioabsorbable gelatin tip which can be deposited at biopsy or puncture sites and assist in achieving hemostasis during a biopsy or venosection procedure. U.S. Patent No. 5,443,481 to Lee describes a method of obtaining hemostasis after an intravascular procedure by applying a hemostatic material to the area of the puncture site after the removal of the access device used during the procedure. U.S. Patent No. 5,292,332 to Lee describes a device for sealing a blood vessel puncture site by the insertion of a hemostatic plug into the vessel puncture site. The present invention is believed to overcome most of the disadvantages of the previous methods which require enlarging the blood vessel puncture site, removal of the access device or both before any hemostatic material is placed..

Numerous materials and methods have been proposed for closure of arteries or other blood vessels accessed during catheterization procedures. These various materials and techniques include sutures, staples, cautery, plugs constructed of collagen, gelfoam, and other biomaterials, slurries of microfibrillar collagen combined with procoagulants such as

thrombin, and fibrin glue. The ideal material would be thrombogenic, nonimmunogenic, and bioresorbable, self-adhesive, radiopaque and would be of an appropriate viscosity to allow precise placement outside the vessel wall with relatively little chance of inadvertent placement of the material into the vessel lumen. For some devices, the use of a liquid, slurry, gel, paste, or foam would be preferred over a solid material, since relatively more volume of the former substances can be placed compared to the latter substance in low profile delivery systems. The present invention addresses many of the problems with existing materials and methods.

Summary of the Invention

The present invention comprises a vascular access device with a needle with an access lumen, with which to obtain vascular access, at least one additional lumen for the infusion of a hemostatic composition, and a means of infusing the composition at the site of vascular access, in order to achieve hemostasis as part of an intravascular procedure. One embodiment of the invention contains two or more infusion lumens, for the infusion of different components of the hemostatic composition. The device is for use in any blood vessel that would normally be used for such procedures, including arteries and veins. The infusion lumen or lumens and the access lumen are arranged concentrically, or optionally in a parallel manner adjacent to one another. In a concentric arrangement the infusion lumen or lumens are arranged around the access lumen. In one preferred embodiment the infusion lumens terminate in a mixing chamber, which optionally includes a mesh or a series of baffles to permit more homogeneity via mixing of the components of the hemostatic composition.

The present invention includes a method of achieving hemostasis during an intravascular procedure. The vascular access device of the present invention is inserted into a blood vessel and advanced until the tip and opening of the access lumen is in the blood vessel but the opening(s) of the infusion lumen(s) are adjacent to the exterior of the vessel wall. Thereafter, the hemostatic composition is infused around the vascular puncture site, flow of the composition into the vessel being prevented by the presence of the needle in the puncture site. After the hemostatic composition is infused the vascular procedure is carried out in the usual manner.

One embodiment of the invention comprises a vascular access device with a hemostatic plug which is compressed and constrained by a deployment sheath, which is removable by retraction or by being peeled away once the hemostatic plug is in the desired location. The invention includes a method of using the vascular access device to achieve hemostasis during an intravascular procedure. The access device is inserted and advanced until the tip of the access lumen is in the lumen of the blood vessel. The access device is further advanced until the hemostatic plug abuts the vessel wall and the deployment sheath is then removed, allowing the plug to expand. The device then is removed, being replaced with the usual type of device used for such intravascular procedures. The deployment sheath is of a retractable or peel away design. In another embodiment, the device comprises a hemostatic plug and deployment sheath as well as a lumen through which a guidewire can be fed. The blood vessel is punctured and a guidewire inserted. Thereafter, the guidewire is inserted into the lumen and the device is advanced over the guidewire until the plug is positioned against the vessel wall. The deployment sheath is removed and the plug is permitted to expand.

Optionally, the device includes a channel or lumen through which extravasated blood can flow when the plug is appropriately positioned against the vessel wall. Optionally, the hemostatic plug of the present invention includes a removal filament for the removal of a maldeployed plug.

The hemostatic compositions and plug are composed of compounds which can achieve hemostasis, and include but are not limited to fibrin glue/thrombin, calcium alginate/ionic calcium, sodium alginate/ionic calcium, collagen paste, or synthetic materials. One embodiment of the present invention is the use of alginate compound for the purpose of achieving hemostasis during intravascular and other medical procedures. These hemostatic compounds contain a cationic salt, preferably calcium chloride, guluronic acid and/or mannuronic acid and a liquid or other medium in order to produce a compound which is a solid, a liquid, a gel, or a foam. Optionally the hemostatic composition or plug is rendered radiopaque by the addition of contrast or other radiopaque material.

Brief Description of the Drawings

Other objects and many of the attendant advantages of the present invention will be appreciated by a reading of the detailed description of the invention, especially when considered in conjunction with the accompanying drawings, which are provided for illustration and are not intended to limit the scope of the present invention.

FIG. 1 is a longitudinal cross sectional view of a first preferred embodiment of the invention showing the construction of the infusion lumens but without the access lumen shown.

FIG. 2A is a longitudinal cross sectional view of the first preferred embodiment with a side by side arrangement of the access and infusion lumens

FIG. 2B is a longitudinal cross sectional view of a preferred embodiment with a co-axial arrangement of the infusion and access lumens.

FIG. 2C is a transverse cross-sectional view of the device shown in FIG. 2B along plane 10.

FIG. 3A is a longitudinal cross-sectional view of the distal end of a preferred embodiment with a tri-axial arrangement of the lumens and with a mixing chamber.

FIG. 3B is a transverse section of the portion of the invention shown in FIG. 3A

FIG. 4 is a longitudinal cross-sectional view of a second preferred embodiment of the present invention comprising a hemostatic plug on the access device .

FIG. 5 is a longitudinal cross-sectional view of a preferred embodiment for the deployment of a hemostatic plug after vascular access has been obtained

FIG. 6 is a longitudinal cross sectional view of the distal portion of another preferred embodiment of the invention depicted in FIG. 5

FIGS. 7 A - G show various stages in the application of one preferred method of using the device depicted in Figure 5

FIG. 7A shows a angiography needle inserted in a blood vessel, with a guidewire through the bore of the needle.

FIG. 7B shows the guidewire in place after removal of the angiography needle

FIG. 7C shows the device of FIG. 5 being fed down the guidewire

FIG. 7D shows the hemostatic plug in place against the vessel wall.

FIG. 7E shows the expanded hemostatic plug after withdrawal of the deployment sheath.

FIG. 7F shows the plug in place after removal of the device

FIG. 7G shows the hemostatic plug in place with an angiographic sheath being fed over the guidewire into the vessel after completion of the procedure.

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Detailed Description of the Invention

The present invention applies to any technique which is performed using percutaneous vessel (artery or vein) puncture including but not limited to diagnostic and interventional
10 radiology or cardiology. When an artery or vein is punctured, an opening in the vessel wall is created and a catheter or other object is placed in the opening. This is usually but not always performed, using a Seldinger-type technique. Subsequently, the vessel requires closure by some mechanism. Existing devices for vessel closure are placed after insertion of and/or removal of vascular catheters or sheaths, the placement of which result in the creation of large
15 holes within the vessel wall. Additionally, when existing devices are placed the exact location of the vessel wall is not known, because the exact location of the vessel wall is only known at the time of placing the puncture needle through the vessel wall and before the placement, for example, of vascular catheters and sheaths.

20 One preferred embodiment of the present invention is a device for placing closure materials, including but not limited to either single- or multi-component liquids, gels, or slurries, immediately outside the vessel wall, while greatly reducing the risk of inadvertent placement of the material into the lumen of the vessel. The vascular access device is an

improvement on arterial or venous entry needles, which are used to perform the initial blood vessel puncture. Preferred embodiments of the vascular access device are shown in Figures 2A and 2B. Referring to Figure 2, the device which has a proximal end 30 and a distal end 20, comprises a needle 15, which is a hollow, preferably cylindrical metal device, with a longitudinal bore or access lumen 7 extending from the proximal end 30 to the distal end 20. At the distal end, the needle has a sharp tip 8 for penetration through the vessel wall and entry into the vessel lumen. The present invention has one, additional longitudinally oriented infusion lumen 1, or optionally more than one additional longitudinally oriented infusion lumen 2, which extend from the proximal portion of the device towards the distal end of the device generally parallel to the access lumen, terminating with one, or optionally more than one, opening 4 proximal to the distal opening of the access lumen 8. The distance from the distal opening of the access lumen 8 to the distal opening, or optionally openings, of the infusion lumen, or optionally lumens 4, preferably is from about 2 mm to about 10 mm, more preferably from about 3 mm to about 6 mm, most preferably about 5 mm. As shown in Figure 2A and in Figure 1, in one preferred embodiment of the present invention the various lumens are arranged in a generally parallel manner adjacent to one another. In a second preferred embodiment, depicted in Figures 2B and 2C, the lumens are arranged in a concentric manner, co-axially in a device with two lumens, or optionally tri-axially in a device with three lumens. Shown in Figure 2C is a cross-sectional transverse view along plane 10 in FIG. 2B, in this embodiment, the access lumen 7 is the central lumen with a first infusion lumen 1, and optionally a second infusion lumen 2, arranged around the access lumen 7. Optionally, a device will have two or more infusion lumens with distal openings that feed into a mixing chamber 3, permitting the mixing of two or more components of a hemostatic composition.